

Appl. No.: 09/601,028
Amdt. dated 01/12/2005
Reply to Office action of July 15, 2004

REMARKS/ARGUMENTS

This amendment is responsive to the Office Action dated July 15, 2004. Claims 1 and 38 - 57 were previously pending in the application, but Claims 38 - 52 are withdrawn subject to a restriction requirement. Claims 1 and 53 - 57 are rejected. By way of this amendment, the Applicant has not cancelled, added, or amended any Claims. Accordingly, Claims 1 and 38 - 57 remain under consideration.

Claim 1 has been rejected under 35 USC 103(a) over Chow et al. ('729 patent) in view of Gerhart et al. ('112 patent) further in view of Sander et al ('629 patent). However, it is respectfully submitted that the Office Action has attempted to construct the claimed invention by selecting and combining elements from the three references without any suggestion or motivation to do so. Such combination would only be made in hindsight of Applicant's disclosure. And, even if combined, the references do not teach or suggest the claimed invention.

By way of background, the present invention is directed to a pharmaceutical-containing composition that comprises a bioresorbable compound comprising calcium, oxygen and phosphorous wherein a portion of at least one of these elements is substituted with an element having an ionic radius of approximately 0.1 to 0.6Å. The compound itself is bioresorbable and the compound contains a substitution of the calcium, oxygen or phosphorous with another element of certain size in order that it can enter the crystal structure of the compound. The composition of the bioresorbable biomaterial, size of the substitution element, and inclusion of a pharmaceutical agent are each recited in Claim 1.

The '729 patent is directed to compositions which convert to hydroxyapatite upon setting. As discussed at length in the specification, the recited compound has been tested and found to be distinct from hydroxyapatite. The '729 patent does not disclose elemental substitution of the hydroxyapatite. Even if the compounds were assumed to be similar, the '729 patent fails to teach or suggest use of the disclosed compound with the drug of the '112 patent or matrix materials in the '629 patent.

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The '112 patent is directed to a bone cement comprising a calcium phosphate ceramic and resorbable calcium salt dispersed in a cross-linked biodegradable polyester matrix. The disclosed composition may contain drugs such as antibiotics. The '112 patent does not disclose elemental substitution of the ceramic material. The '112 patent fails to teach or suggest use of the '729 compound in place of the disclosed calcium phosphate ceramic composition and provides no motivation to use the composition with the matrix materials of the '629 patent.

The '629 patent is directed to a composition for bone repair which comprises biocompatible particles of a polymer dispersed in a matrix. The Office Action uses the '629 patent to show substitution of a biomaterial compound. However, substitution disclosed in the patent is quite different from the elemental substitution recited in Claim 1. Referring to col. 5, lines 35 - 42, the disclosed substitution is that of matrix materials, such as cellulose ethers, collagen, or hyaluronic acid, within a liquid medium. In contrast, the substitution within the biomaterial compound as recited in Claim 1 is an elemental substitution of a size to fit in the crystal lattice structure of the recited compound. The '629 makes no such disclosure, and also fails to provide motivation for the combination of the '629 matrix materials with the hydroxyapatite of the '729 patent or the drugs of the '112 patent.

As shown above, the references are concerned with distinct compounds and different uses of the technology and do not provide motivation for combination of the references. Thus, the references are improperly combined and the rejection should be withdrawn.

Even if combined, the references do not teach each and every element of the claimed invention. The combination of references fails to teach a composition comprising a compound with the recited elemental substitution. In short, no elemental substitution is disclosed in any of the references. The elemental substitution in the compound creates a new compound having improved resorbability characteristics such that it can be integrated into in vivo or in vitro bone. Thus, the combination of reference fails to disclose the claimed composition and the rejection should be withdrawn.

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Claims 1 and 53-57 are rejected under 35 USC 103(a) over Chow et al. ('729 patent) in view of Gerhart et al. ('112 patent) further in view of Sander et al ('629 patent) and Kasuga et al ('878 patent). The deficiencies of the '729, '112, and '629 patents, used alone or in combination, have been discussed above.

The '878 patent is directed to an inorganic biomaterial which is a bioactive glass. The implant of the '878 patent is a physical dispersion of crystallized glass or calcium phosphate within a skeleton of zirconia, which provides for increased mechanical properties. The fact that Kasuga is directed to a "glass" structurally identifies the material as being different from that presently claimed. It is only in the later steps of Kasuga's process that the glass is heated to form a crystallized powder which is then mixed with zirconia or alumina that acts to "partially stabilize zirconia" by which is meant that the zirconia is prepared to attain high strength and high toughness with respect to stress-induced transformation (column 6, lines 38-44) such that it can be used as a biomaterial for artificial bones and dental implants.

There is no teaching or suggestion to use the glass modification procedures of the '878 patent with any of the references discussed above. Further, there is no disclosure of elemental substitution, much less elemental substitution of a bioresorbable compound, and the combination of the four cited references still fails to teach or suggest the elemental substitution recited in Claim 1. Therefore, the rejection in view of the combination of the '729, '112, '629, and '878 patents should be withdrawn.

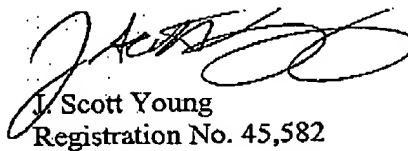
In view of the amendments and remarks made above, Applicant submits that the pending claims are now in condition for allowance. Applicant respectfully requests that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned by telephone.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of

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this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

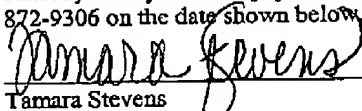
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Tamara Stevens

January 12, 2005
Date